



Form 10 & 50 - HRT Management and Safety Interview, Report of Vaginal Bleeding

Data File: f10\_50\_ct\_pub      File Date: 07/19/2007      Structure: Multiple rows per participant      Population: HT participants

Participant ID

Variable # 1

Sas Name: ID

Sas Label: Participant ID

Usage Notes: none

Categories: Study: Administration

F10/50 Days since randomization

Days between randomization and initiation of form

Variable # 2

Sas Name: F1050DYS

Sas Label: F10/50 Days since randomization

Usage Notes: none

Categories: Study: Administration

N	Min	Max	Mean	Std Dev
330977	2	4041	1205.8092	856.19202

F10/50 Visit type

Variable # 3

Sas Name: F1050VTYP

Sas Label: Visit type

Usage Notes: none

Categories: Study: Administration

Values	N	%
2      Semi-Annual Visit	153,012	46.2%
3      Annual Visit	142,612	43.1%
4      Non-Routine Visit	9,260	2.8%
5      6-Week HRT Phone Call	26,093	7.9%
	330,977	

F10/50 Visit year

Visit year for which this form was collected.

Variable # 4

Sas Name: F1050VY

Sas Label: Visit year

Usage Notes: none

Categories: Study: Administration

N	Min	Max	Mean	Std Dev
295623	1	11	3.87344	2.23426

Had a hysterectomy

Has the participant had a hysterectomy?

Variable # 5

Sas Name: HYST

Sas Label: Had a hysterectomy

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Reproductive

Values	N	%
0      No	188,358	56.9%
1      Yes	132,566	40.1%
.      Missing	10,053	3.0%
	330,977	



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Had vaginal bleeding

Variable # 6

Sas Name: VAGBLEED

Sas Label: Had vaginal bleeding

Usage Notes: none

Categories: Reproductive: Menstrual

Values		N	%
0	No	299,586	90.5%
1	Yes	27,412	8.3%
.	Missing	3,979	1.2%
		330,977	

How heavy was vaginal bleeding

Variable # 7

Sas Name: HEAVYBLD

Sas Label: How heavy was vaginal bleeding

Usage Notes: Not collected on all versions of Form 10.

Categories: Reproductive: Menstrual

Values		N	%
1	Spotting - approx 1 pad/day	19,111	5.8%
2	Light - 2 or 3 pads/day	3,317	1.0%
3	Moderate - 4 to 7 pads/day	2,360	0.7%
4	Severe - 8 or more pads/day	332	0.1%
.	Missing	305,857	92.4%
		330,977	

Days from randomization to vaginal bleeding start

Variable # 8

Sas Name: STARTDY

Sas Label: Days from randomization to vaginal bleeding start

Usage Notes: Not collected on all versions of Form 10.

Categories: Reproductive: Menstrual

N	Min	Max	Mean	Std Dev
24618	-350	3466	586.71399	654.9887

Did vaginal bleeding start and stop again

Variable # 9

Sas Name: INTERMIT

Sas Label: Did vaginal bleeding start and stop again

Usage Notes: Not collected on all versions of Form 10.  
Not collected on all versions of Form 50.

Categories: Reproductive: Menstrual

Values		N	%
0	No	7,862	2.4%
1	Yes	16,851	5.1%
.	Missing	306,264	92.5%
		330,977	



Are you bleeding from the vagina now

Variable # 10

Sas Name: BLEEDNOW

Sas Label: Are you bleeding from the vagina now

Usage Notes: Not collected on all versions of Form 10.

Categories: Reproductive: Menstrual

Values		N	%
0	No	20,579	6.2%
1	Yes	4,667	1.4%
.	Missing	305,731	92.4%
		330,977	

Days from randomization to vaginal bleeding stop

Variable # 11

Sas Name: STOPDY

Sas Label: Days from randomization to vaginal bleeding stop

Usage Notes: Not collected on all versions of Form 10.  
Sub-question of "Are you bleeding from the vagina now".

Categories: Reproductive: Menstrual

N	Min	Max	Mean	Std Dev
19124	-327	3468	663.08006	655.88963

Had any breast tenderness

Since your last contact, have you had any breast tenderness?

Variable # 12

Sas Name: BRSTTEND

Sas Label: Had any breast tenderness

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Breast

Values		N	%
0	No	133,998	40.5%
1	Yes	11,014	3.3%
.	Missing	185,965	56.2%
		330,977	

Breast tenderness severity

Was your breast tenderness mild, moderate, or severe?

Variable # 13

Sas Name: SEVTEND

Sas Label: Breast tenderness severity

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.  
Sub-question of F10 V7 Q7 "Had any breast tenderness"

Categories: Medical History: Breast

Values		N	%
1	Mild	8,224	2.5%
2	Moderate	2,159	0.7%
3	Severe	467	0.1%
.	Missing	320,127	96.7%
		330,977	



Any changes in your breasts

Have you noticed any changes in your breasts (new lumps, nipple discharge, or skin changes)?

**Variable #** 14

**Sas Name:** BRSTCHNG

**Sas Label:** Any changes in your breasts

**Usage Notes:** Not collected on Form 50.

**Categories:** Medical History: Breast

Values		N	%
0	No	317,032	95.8%
1	Yes	9,607	2.9%
.	Missing	4,338	1.3%
		330,977	

Taking or prescribed Corticosteroids

Are you now taking, or has a doctor prescribed, any Corticosteroids (such as Prednisone, Decadron, Medrol in pill form)?

**Variable #** 15

**Sas Name:** CORTICOS

**Sas Label:** Taking or prescribed Corticosteroids

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Medications

Values		N	%
0	No	299,156	90.4%
1	Yes	3,483	1.1%
.	Missing	28,338	8.6%
		330,977	

Taking or prescribed blood thinning medications

Are you now taking, or has a doctor prescribed any blood thinning medications (such as Coumadin or Warfarin)?

**Variable #** 16

**Sas Name:** ANTICOAG

**Sas Label:** Taking or prescribed blood thinning medications

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Medications

Values		N	%
0	No	298,736	90.3%
1	Yes	3,713	1.1%
.	Missing	28,528	8.6%
		330,977	

Taking or prescribed Estrogen

Are you now taking, or has a doctor prescribed Estrogen?

**Variable #** 17

**Sas Name:** ESTROGEN

**Sas Label:** Taking or prescribed Estrogen

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Medications  
Reproductive: Hormones

Values		N	%
0	No	296,900	89.7%
1	Yes	5,702	1.7%
.	Missing	28,375	8.6%
		330,977	



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## Taking or prescribed Progesterone

Are you now taking, or has a doctor prescribed Progesterone?

Variable # 18

Sas Name: PROGEST

Sas Label: Taking or prescribed Progesterone

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Medications  
Reproductive: Hormones

Values		N	%
0	No	300,052	90.7%
1	Yes	2,442	0.7%
.	Missing	28,483	8.6%
		330,977	

## Taking or prescribed Testosterone

Are you now taking, or has a doctor prescribed Testosterone?

Variable # 19

Sas Name: TESTOST

Sas Label: Taking or prescribed Testosterone

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Medications  
Reproductive: Hormones

Values		N	%
0	No	302,183	91.3%
1	Yes	199	0.1%
.	Missing	28,595	8.6%
		330,977	

## Taking or prescribed Tamoxifen

Are you now taking, or has a doctor prescribed Tamoxifen, Raloxifene (Evista) or other medications know as SERMS?

Variable # 20

Sas Name: TAMOXIF

Sas Label: Taking or prescribed Tamoxifen

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Medications  
Reproductive: Hormones

Values		N	%
0	No	301,085	91.0%
1	Yes	1,283	0.4%
.	Missing	28,609	8.6%
		330,977	

## Endometrial hyperplasia

Since your last contact has a doctor told you that you had Endometrial hyperplasia?

Variable # 21

Sas Name: ENDOHYP

Sas Label: Endometrial hyperplasia

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.**Categories:** Medical History: Reproductive

Values		N	%
0	No	300,153	90.7%
1	Yes	190	0.1%
.	Missing	30,634	9.3%
		330,977	



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High triglycerides in blood

Since your last contact has a doctor told you that you had high triglycerides in your blood (triglycerides are not the same as cholesterol)?

Variable # 22

Sas Name: HIGHTRIG

Sas Label: High triglycerides in blood

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Other Disease/Condition

Values		N	%
0	No	294,723	89.0%
1	Yes	7,439	2.2%
.	Missing	28,815	8.7%
		330,977	

Were your triglycerides over 1000 (mg/dl)

Variable # 23

Sas Name: TRIG1000

Sas Label: Were your triglycerides over 1000 (mg/dl)

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.  
Sub-question of F10 V7 Q11.2 "High triglycerides in blood".

Categories: Medical History: Other Disease/Condition

Values		N	%
0	No	5,037	1.5%
1	Yes	50	0.0%
.	Missing	325,890	98.5%
		330,977	

Blood clot to your leg or lung

Since your last contact has a doctor told you that you had a blood clot to your leg or lung?

Variable # 24

Sas Name: BLDCLLOT

Sas Label: Blood clot to your leg or lung

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Cardiovascular

Values		N	%
0	No	301,777	91.2%
1	Yes	657	0.2%
.	Missing	28,543	8.6%
		330,977	

Melanoma of skin

Since your last contact has a doctor told you that you had melanoma of skin?

Variable # 25

Sas Name: MELANOMA

Sas Label: Melanoma of skin

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Cancer

Values		N	%
0	No	302,199	91.3%
1	Yes	229	0.1%
.	Missing	28,549	8.6%
		330,977	



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Heart attack or stroke

Since your last contact has a doctor told you that you had a heart attack or stroke?

Variable # 26

Sas Name: HEARTSTK

Sas Label: Heart attack or stroke

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Cardiovascular

Values		N	%
0	No	301,042	91.0%
1	Yes	1,356	0.4%
.	Missing	28,579	8.6%
		330,977	

Meningioma, or tumors in the brain

Since your last contact has a doctor told you that you had meningioma, or tumors in the brain?

Variable # 27

Sas Name: MENINGIO

Sas Label: Meningioma, or tumors in the brain

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Cancer

Values		N	%
0	No	302,093	91.3%
1	Yes	177	0.1%
.	Missing	28,707	8.7%
		330,977	

Breast cancer

Since your last contact has a doctor told you that you had breast cancer?

Variable # 28

Sas Name: BRSTCANC

Sas Label: Breast cancer

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Cancer

Values		N	%
0	No	144,352	43.6%
1	Yes	431	0.1%
.	Missing	186,194	56.3%
		330,977	

Gall bladder disease

Since your last contact has a doctor told you that you had gall bladder disease?

Variable # 29

Sas Name: GALLBLAD

Sas Label: Gall bladder disease

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Medical History: Other Disease/Condition

Values		N	%
0	No	71,964	21.7%
1	Yes	370	0.1%
.	Missing	258,643	78.1%
		330,977	



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Problems with your pancreas

Since your last contact has a doctor told you that you had problems with your pancreas?

**Variable #** 30

**Sas Name:** PANCREAS

**Sas Label:** Problems with your pancreas

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Medical History: Other Disease/Condition

Values		N	%
0	No	72,161	21.8%
1	Yes	116	0.0%
.	Missing	258,700	78.2%
		330,977	

Participant advised to continue study medications

Resulting action from participant reports of symptoms or concerns: Participant reassured and advised to continue with current study medications.

**Variable #** 31

**Sas Name:** CONTMEDS

**Sas Label:** Participant advised to continue study medications

**Usage Notes:** Not collected on all versions of Form 10.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	56,659	17.1%
1	Yes	190,667	57.6%
.	Missing	83,651	25.3%
		330,977	

Participant advised to return for evaluation

Resulting action from participant reports of symptoms or concerns: Participant advised to return to clinic for evaluation.

**Variable #** 32

**Sas Name:** RTRNEVAL

**Sas Label:** Participant advised to return for evaluation

**Usage Notes:** Not collected on all versions of Form 10.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	246,213	74.4%
1	Yes	1,113	0.3%
.	Missing	83,651	25.3%
		330,977	

Consulting gynecologist notified

Resulting action from participant reports of symptoms or concerns: Consulting gynecologist notified.

**Variable #** 33

**Sas Name:** GYNNOTE

**Sas Label:** Consulting gynecologist notified

**Usage Notes:** Not collected on all versions of Form 10.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	244,911	74.0%
1	Yes	2,415	0.7%
.	Missing	83,651	25.3%
		330,977	





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Participant referred to primary physician

Resulting action from participant reports of symptoms or concerns: Participant referred to primary physician.

Variable # 34

Sas Name: PHYSNOTE

Sas Label: Participant referred to primary physician

Usage Notes: Not collected on all versions of Form 10.

Categories: Study Interventions: HRT Intervention/Management

Values		N	%
0	No	246,102	74.4%
1	Yes	1,224	0.4%
.	Missing	83,651	25.3%
		330,977	

Medications changed or stopped

Resulting action from participant reports of symptoms or concerns: Medications changed or stopped.

Variable # 35

Sas Name: MEDCHNG

Sas Label: Medications changed or stopped

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Study Interventions: HRT Intervention/Management

Values		N	%
0	No	235,989	71.3%
1	Yes	9,970	3.0%
.	Missing	85,018	25.7%
		330,977	

Other action taken

Resulting action from participant reports of symptoms or concerns: Other.

Variable # 36

Sas Name: OTHERACT

Sas Label: Other action taken

Usage Notes: Not collected on all versions of Form 10.

Categories: Study Interventions: HRT Intervention/Management

Values		N	%
0	No	198,305	59.9%
1	Yes	49,021	14.8%
.	Missing	83,651	25.3%
		330,977	



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How often did you take the study pills

Since your last contact, how often did you take the study pills?

Variable # 37

Sas Name: PILLFREQ

Sas Label: How often did you take the study pills

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Study Interventions: HRT Intervention/Management

Values		N	%
0	Not at all	41,862	12.6%
1	Less than once per week	675	0.2%
2	1 - 2 days per week	990	0.3%
3	3 - 4 days per week	5,277	1.6%
4	5 - 6 days per week	9,832	3.0%
5	Every day of the week	245,374	74.1%
.	Missing	26,967	8.1%
		330,977	

How many days missed taking pills in last month

About how many days have you missed taking your pills in the last month?

Variable # 38

Sas Name: DAYSMISS

Sas Label: How many days missed taking pills in last month

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Study Interventions: HRT Intervention/Management

N	Min	Max	Mean	Std Dev
274859	0	31	4.6365	9.88919

Took all pills every day

If there were days you did not take the pills, what were the reasons you didn't: Took all pills every day

Variable # 39

Sas Name: ALLPILLS

Sas Label: Took all pills every day

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Study Interventions: HRT Intervention/Management

Values		N	%
0	No	115,239	34.8%
1	Yes	162,764	49.2%
.	Missing	52,974	16.0%
		330,977	

Experienced symptoms

If there were days you did not take the pills, what were the reasons you didn't: Experienced symptoms

Variable # 40

Sas Name: EXPSYMP

Sas Label: Experienced symptoms

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.

Categories: Study Interventions: HRT Intervention/Management

Values		N	%
0	No	274,501	82.9%
1	Yes	3,502	1.1%
.	Missing	52,974	16.0%
		330,977	



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Forgot pill(s)

If there were days you did not take the pills, what were the reasons you didn't: Forgot pill(s)

**Variable #** 41

**Sas Name:** FRGTPILL

**Sas Label:** Forgot pill(s)

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	218,878	66.1%
1	Yes	59,125	17.9%
.	Missing	52,974	16.0%
		330,977	

Forgot bottle

If there were days you did not take the pills, what were the reasons you didn't: Forgot bottle

**Variable #** 42

**Sas Name:** FRGTBOTL

**Sas Label:** Forgot bottle

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	274,604	83.0%
1	Yes	3,399	1.0%
.	Missing	52,974	16.0%
		330,977	

Needed/Took a break

If there were days you did not take the pills, what were the reasons you didn't: Needed/Took a break

**Variable #** 43

**Sas Name:** TOOKBRK

**Sas Label:** Needed/Took a break

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	275,972	83.4%
1	Yes	2,031	0.6%
.	Missing	52,974	16.0%
		330,977	

Afraid of health problems

If there were days you did not take the pills, what were the reasons you didn't: Afraid of health problems

**Variable #** 44

**Sas Name:** AFRAID

**Sas Label:** Afraid of health problems

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	275,389	83.2%
1	Yes	2,614	0.8%
.	Missing	52,974	16.0%
		330,977	



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Family/Friend recommendation

If there were days you did not take the pills, what were the reasons you didn't: Family/Friend recommendation

**Variable #** 45

**Sas Name:** FAMRCMND

**Sas Label:** Family/Friend recommendation

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	277,872	84.0%
1	Yes	131	0.0%
.	Missing	52,974	16.0%
		330,977	

MD recommendation

If there were days you did not take the pills, what were the reasons you didn't: MD recommendation

**Variable #** 46

**Sas Name:** MDRCMND

**Sas Label:** MD recommendation

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	273,037	82.5%
1	Yes	4,966	1.5%
.	Missing	52,974	16.0%
		330,977	

Didn't have any pills

If there were days you did not take the pills, what were the reasons you didn't: Didn't have any pills

**Variable #** 47

**Sas Name:** NOPILLS

**Sas Label:** Didn't have any pills

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	272,151	82.2%
1	Yes	5,852	1.8%
.	Missing	52,974	16.0%
		330,977	

Other reason for missing pills

If there were days you did not take the pills, what were the reasons you didn't: Other

**Variable #** 48

**Sas Name:** OTHRMISS

**Sas Label:** Other reason for missing pills

**Usage Notes:** Not collected on all versions of Form 10.  
Not collected on Form 50.

**Categories:** Study Interventions: HRT Intervention/Management

Values		N	%
0	No	226,513	68.4%
1	Yes	51,490	15.6%
.	Missing	52,974	16.0%
		330,977	



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Should be put on Intensive Adherence Program

Should participant be put on Intensive Adherence Program (IAP)?

Variable # 49

Sas Name: IAP

Sas Label: Should be put on Intensive Adherence Program

Usage Notes: Not collected on all versions of Form 10.  
Not collected on Form 50.  
Categories: Study Interventions: HRT Intervention/Management

Values		N	%
0	No	269,840	81.5%
1	Yes	5,490	1.7%
.	Missing	55,647	16.8%
		330,977	

Should participant be recontacted in one month

Should participant be recontacted in one month by phone for clinical follow-up

Variable # 50

Sas Name: RECONTAC

Sas Label: Should participant be recontacted in one month

Usage Notes: Not collected on all versions of Form 10.  
Categories: Study Interventions: HRT Intervention/Management

Values		N	%
0	No	247,846	74.9%
1	Yes	7,080	2.1%
.	Missing	76,051	23.0%
		330,977	